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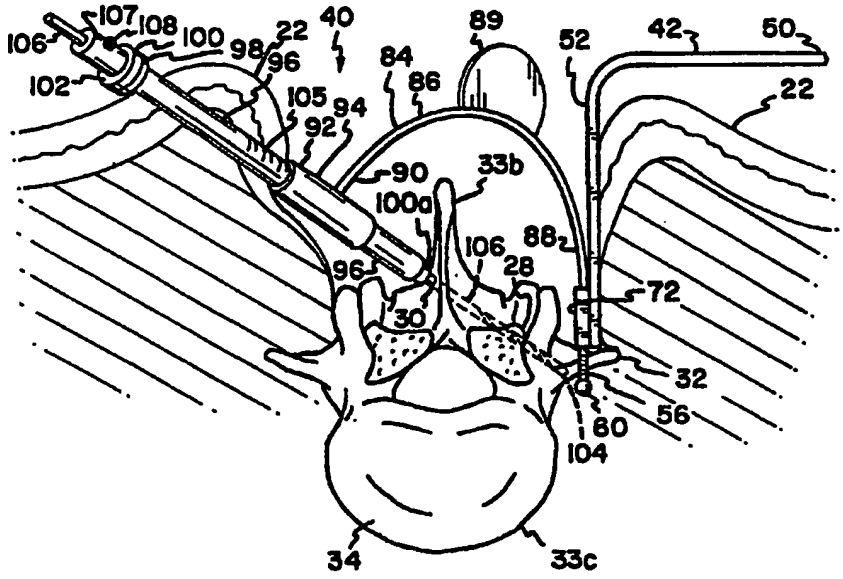

(57) Abstract

A drill guide apparatus (40) includes a retractor assembly (42), a handle (50) and a retractor blade (52) extending from the handle. The retractor blade (52) includes an extension extending from the retractor blade (52). The extension defines an opening for the receipt of a drill bit (104). The extension can be a guide sleeve assembly (92) including a passage (94) therethrough defining the opening, and an arm (109) extending from the body to engage the retractor blade (52). Preferably the guide sleeve assembly (92) is separable from the retractor blade (52).

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DRILL GUIDE APPARATUS AND METHODS INCLUDING SELECTABLE GUIDES

Related Application

The present application is a Continuation-in-Part of Application Serial No. 08/262,959, filed June 21, 1994.

Field of the Invention

The present invention relates to apparatus and methods for drilling holes in a substrate, such as bone, and placement of screws therein.

Background of the Invention

In the field of orthopedics, internal fixation of bony tissues is commonly used to facilitate bone healing for the purposes of promoting fusion, maintaining alignment, and improving patient comfort. Internal fixation can be accomplished in some cases with the use of a bone screw positioned in the bony tissues to be transfixed. Bony tissues subjected to internal fixation generally heal more effectively with less complication than bony tissues not internally fixed.

Spinal fusion is sometimes medically necessary to treat diseased or injured spinal motion segments. Internal fixation may be accomplished in the case of the spine by utilizing a facet screw positioned to join two adjacent vertebra.

When an individual sustains a physical injury or medical disease requiring spinal fusion, the treating physician must make a determination as to whether internal fixation would be allowable or necessary. If the physician should choose to use internal fixation methods, it may be necessary to position a screw or pin within the very complicated and important anatomy of the spine. Unfortunately, the use of screws or pins in internal fixation of the spine is accompanied by complicating

factors including a preferred location which is difficult to access during surgery. During a spinal fixation operation, the patient is placed in position on the operating table and undergoes a surgical incision where natural tissue tension and normal anatomy places the surgeon well away from the delicate spinal anatomy. Additionally, bleeding occurs which interferes with the surgeon's view. Further, the very deep structures including the transverse process and the base of the facet joint are out of view in the typical surgery. Also, there is often little margin for error during the surgical procedure. Placement of facet screws or pins is difficult because of the close proximity to the surrounding bony tissues of the spine, and the patient's neural and vascular anatomy. Efficient and reliable placement of the screws or pins are significant concerns. Both the risk of complications to the patient and the cost of the surgical procedure increase the longer the surgeon takes to install the screws or pins.

There is a need in the art for drill guide apparatus and methods for use in efficient and reliable drilling of holes and positioning of screws, pins or other fixation structures in a substrate, such as the bony structures of a human anatomy, particularly the spine.

Summary of the Invention

The present invention relates to a drill guide apparatus including a retractor assembly having a handle, and a retractor blade extending from the handle at an angle to the handle. The drill guide apparatus includes an extension from the retractor blade with the extension defining an opening for receipt of a drill bit. Preferably, the extension is a guide sleeve assembly including a passage therethrough defining the opening, and an arm extending from the body to engage the retractor

blade. Preferably the guide sleeve assembly is separable from the retractor blade.

The present invention also relates to a method of transfixing a spinal facet joint including the steps of positioning a retractor assembly to engage the spine, mounting a guide sleeve assembly to the retractor assembly, positioning a drill bit in the guide sleeve assembly, drilling a hole in the spine with the drill bit using the guide sleeve assembly as a guide, and inserting a screw into the hole drilled by the drill bit.

The present invention relates to a drill guide apparatus including a retractor assembly having a handle and a retractor blade extending at an angle from the handle, an arch assembly mounted to the retractor assembly, and a guide sleeve assembly mounted to the arch assembly and defining an opening for receipt of a drill bit. The retractor assembly holds back the patient's skin, fat, and muscle tissues and also defines the patient's anatomy and a target zone in the vertebra for the drill bit. The drill guide apparatus controls the location of entry of the drill bit, and the angle of entry.

Following receipt and removal of the drill bit, the guide sleeve assembly receives a screw which is then rotated into the channel in the substrate formed by the drill bit. The drill guide apparatus controls the location of entry of the screw, and the angle of entry.

A washer is preferably provided adjacent to a lower end of the guide sleeve assembly for engagement with the screw as the screw exits the guide sleeve assembly and prior to full rotation of the screw into the substrate. Preferably, the washer is selectively mounted to the guide sleeve assembly during use, thereby allowing hands-free operation of the drill guide apparatus during insertion of the screw. The washer cooperates with the screw to provide increased surface area in engagement with the bone after

tightening down of the screw. A planar or a cup-shaped washer may be provided.

The guide sleeve assembly preferably includes a barrel mounted to the arch assembly, a screw sleeve slidably mounted to the barrel, and a drill sleeve slidably mounted inside the screw sleeve.

The retractor assembly preferably includes an end with a first threadably mounted probe. Preferably, a second threadably mounted probe extends from the retractor assembly and is spaced from the first probe. Preferably, the retractor assembly includes at least three threaded holes in alignment wherein the first and second probes are each positioned in one of the threaded holes. A permanent mount for one or both probes is an option.

The washer preferably includes mating structure for engaging the screw to permit rotation of the washer with the screw, such as during removal of the screw from the substrate when the washer is engaged by a tool. Preferably, the washer includes an outer tool engaging surface along a central projection for use in engagement with the tool.

Preferably, the arch assembly is pivotally mounted to the retractor assembly, and the guide sleeve assembly is slidably mounted to the arch assembly for movement along the arch assembly. However, right and left sided drill guide apparatus are an option if pivotal movement is not desired or sufficiently provided to permit right and left sided use.

The drill guide apparatus preferably includes depth calibration markings on the screw sleeve such that calibration of the depth of the drill bit tip relative to the target zone is known. A drill bit disposed within the inner sleeve includes a drill stop to limit insertion of the drill bit to the target zone.

The present invention also relates to methods of joining two substrate members together including the steps of positioning a guide sleeve assembly adjacent to one of the substrate members, positioning a drill bit in the guide sleeve assembly, drilling a hole into at least one of the two substrate members with the drill bit, positioning a screw in the guide sleeve assembly, and rotating the screw into the two substrate members. Preferably, the method includes utilizing a retractor assembly to engage the spine to define the anatomy and a target zone for the drill bit wherein the guide sleeve assembly is mounted to the retractor assembly. The method further preferably includes positioning a washer adjacent at end of the guide sleeve assembly wherein the head of the screw engages the washer after passing through the guide sleeve assembly. In the preferred method, rotation of the screw and the washer as a unit for removal out of the two substrate members is an option, if desired.

Instead of a screw, other fixation structures can be utilized, including pins. While the preferred substrate is bone, specifically the spine, other bony tissues or even other substrates can be fixated with the use of the drill guide apparatus.

Another aspect of the present invention relates to a kit arrangement and method wherein a plurality of drill guide apparatus are provided, each having a variation in configuration to adjust to variations in the substrate. For example, variations in the size and shape of the individual vertebra of a patient may occur. Also, variations in size and shape of the vertebrae between patients may occur. The location of the drill guide portion from the retractor portion can be varied, and so can the angle. Preferably, the drill guide portion is separable from the retractor portion for useability of the retractor portion with different drill guide portions.

Brief Description of the Drawings

In the drawings in which like reference numerals refer to corresponding parts of preferred embodiments of the present invention throughout the several views:

Figure 1 is a view from above of a lumbar spine as seen through a posterior incision during surgery, wherein the patient's head would be to the left of the portion shown;

Figure 2 is a side view of the lowest three lumbar vertebrae and sacrum;

Figure 3 is an enlarged side view of a lumbar vertebra and a portion of the drill guide apparatus resting around the transverse process.

Figure 4 is a view from above the vertebra of Figure 3 showing portions of the drill guide apparatus resting around the transverse process.

Figure 5 is an end view of the vertebra of Figure 3 showing the drill guide apparatus during the drilling operation;

Figure 6 is an end view of the vertebra shown in Figure 5 with the drill guide apparatus during the screw positioning operation;

Figure 7 is an end view of the vertebra shown in Figures 5 and 6 showing drilling and positioning a screw in the opposite direction of that shown in Figures 5 and 6;

Figure 8 is an end view of the vertebra shown in Figures 5 through 7 showing two screw assemblies in position;

Figure 9 is an enlarged side view of a first embodiment of a screw;

Figure 10 is an enlarged top view of a first embodiment of a washer;

Figure 11 shows a screw assembly including the screw of Figure 9, and the washer of Figure 10 mounted to a substrate;

Figure 12 shows a portion of an alternative head for the screw of Figure 9;

Figure 13 shows an alternative washer to the washer of Figure 10, and showing the washer mounted to the screw of Figure 9;

Figure 14 shows the screw and washer of Figure 13 mounted to a substrate, and a tool usable to remove the screw and the washer from the substrate;

Figure 15 is a top view of a portion of the drill guide apparatus showing movement of the arch assembly relative to the retractor assembly;

Figure 16 shows an alternative mounting arrangement between the barrel of the guide sleeve assembly and the arch assembly wherein the barrel is slidably moveable and lockable relative to the arch assembly;

Figure 17 is a top view of a portion of the alternative mounting arrangement between the barrel of the guide sleeve assembly and the arch assembly;

Figure 18 is an alternative guide sleeve assembly including a shortened drill sleeve, and the washer of Figure 13 mounted to the screw sleeve during the drilling operation;

Figure 19 shows the guide sleeve assembly of Figure 18 during the screw placement operation prior to full engagement of the screw and the washer;

Figure 20 is an alternative drill bit shown with the screw sleeve of the guide sleeve assembly of Figure 1 during the drilling operation;

Figure 21 shows a drill bit like that of Figure 20 with a reinforcing sleeve during the initial drilling operation;

Figure 22 shows an end of the drill bit of Figure 21;

Figure 23 is a portion of an alternative retractor assembly;

Figures 24 and 25 show an alternative removable guide sleeve assembly for attachment to the retractor assembly of Figure 23;

Figures 26 and 27 show two enlarged alternative guide sleeve assemblies to the guide sleeve assembly shown in Figures 24 and 25;

Figure 28 shows a drill bit useable with the guide sleeve assemblies of Figures 24-27;

Figure 29 shows the retractor assembly of Figure 23 mounted to the guide sleeve assembly of Figures 24 and 25 during use; and

Figure 30 is a portion of an alternative retractor assembly and guide sleeve assembly including a spring loaded lock for locking the guide sleeve assembly to the retractor assembly.

Detailed Description of the Preferred Embodiments

The present invention facilitates minimized dissection and retraction of the patient during spinal surgery. The present invention also allows for accurate positioning and placement of a drill bit and a screw in difficult to access substrates, such as the patient's spine. The drill guide apparatus of the present invention includes a retractor assembly for retracting tissue, and a guide sleeve assembly for guiding either or both a drill bit and a screw with respect to location, angle, and depth, if desired. Preferably, linking structure links the retractor assembly and the guide sleeve assembly.

Referring now to the drawings, and to Figure 1 in particular, a diagrammatic representation of a spinal operation with respect to a patient's back 20 is illustrated. The skin 22 of patient 20 is provided with an elliptical surgical incision 24. Through this incision, the dorsal vertebral anatomy 26 is visible including a facet joint 28 between adjacent vertebrae. A proposed

insertion point 30 of a facet screw on the dorsal lamina, and a base of a transverse process 32 are also shown. The transverse process 32 is used to define the anatomy for the surgeon for accurate placement of a facet screw through insertion point 30 at facet joint 28.

Referring now to Figure 2, the lower three vertebrae 33a, 33b, 33c articulate with one another in sequential fashion and then with the sacrum 33d. Beneath skin 22 is visible a side view of facet joint 28. The vertebral body 34 of vertebra 33c and the articulating disc 36 are also shown.

Referring now to Figures 3 through 6, a drill guide apparatus 40 is shown for use in placement of a facet screw through facet joint 28. A retractor assembly 42 is placed within the surgical wound. As shown in Figure 5, retractor assembly 42 includes a handle 50 and a retractor blade 52 extending at an angle from handle 50. Retractor blade 52 is usable for holding skin 22 and other tissue (fat, muscle) away from the surgical area. Retractor blade 52 includes an end 54 with a blunt probe 56 extending from end 54. A second probe 66 extends from end 54 and is spaced from first probe 56. As shown in Figure 3, first probe 56 and second probe 66 are positioned around transverse process 32 defining between them the target zone 104 above vertebral body 34 and disc 36. First and second probes 56, 66 and end 54 of retractor assembly 42 cooperate to surround the base of transverse process 32 on three sides to securely engage the spine and define the anatomy.

Retractor assembly 42 is usable with a single probe, either first probe 56 or second probe 66, in one embodiment. For example, in a procedure to transfix a vertebra with the sacrum, only one probe may be useable due to the configuration of the dorsal anatomy 26 of the patient. Even with respect to transfixing two vertebrae, only a single probe may be desired by the surgeon. In that

case, either single probe 56, 66 can be positioned offset relative to a central axis of retractor blade 52, in much the same manner as shown in Figure 3, where both probes 56, 66 are illustrated.

Retractor assembly 42 reaches down to and around pertinent portions of the bone anatomy, both steadying the retractor and defining the important anatomy, the base of the transverse process or similar anatomy defined between the probes 56, 66. Often, end 54 of retractor assembly 42 may not even be visible to the surgeon once placed to define the anatomy and the target zone.

During use of retractor assembly 42, end 54 cooperates with a single probe 56, 66 (if only a single probe is provided) to surround the bone on two sides. When retractor assembly 42 is provided with two probes 56, 66, a secure three-sided surround of the bone is provided, such as shown in Figure 3.

First probe 56 is provided with a blunt tip 60 and a threaded shaft 58 extending therefrom to end 54. Such construction permits threaded adjustment of the length of extension of blunt end 60 from end 54. Moreover, such threaded engagement permits removal of probe 56 from end 54, if desired. Second probe 66 also includes a similarly configured blunt tips 70 and a threaded shaft 68. The threaded configuration permits removal of second probe 66, or adjustability with respect to the extension of blunt end 70 from end 54.

A mount 72 forming end 54 of retractor assembly 42 includes a plurality of holes 74, 76, 78, 80, 82 as shown in Figure 4. Preferably, holes 74, 76, 78, 80, 82 are threaded for receipt of a probe, as desired. While five holes are shown in Figure 4, any number are possible, including 3 or 7. As will be described below, at least one of the holes, the central hole typically, is preferably usable with an arch assembly. It is to be appreciated that

either or both of probes 56, 66 can be permanently mounted to end 54 of retractor assembly 42.

As shown in Figure 4, transverse process 32 is visible beneath the retractor assembly 42 between the tips 60, 70 of probes 56, 66. Insertion point 30 on the dorsal lamina is a specific point judged by the surgeon to be the preferred point of insertion for the facet screw to transfix facet joint 28. A preferred insertion zone 30a is generally defined as shown in Figure 4 and is also known as the contralateral region to the intended facet joint (translaminar). Also shown in Figure 4 is an alternative insertion zone 30b which is ipsilateral to the intended facet joint (classic facet screw).

Referring now to Figure 5, retractor assembly 42 is shown retracting skin 22 and the soft tissues of the patient. First probe 56 and second probe 66 are positioned around transverse process 32 (in Figure 5 only first probe 56 is visible). Extending upward from mount 72 of retractor assembly 42 is an arch assembly 84. Arch assembly 84 includes an arch 86 extending from proximal end 88 to distal end 90. At distal end 90, arch assembly 84 is mounted to barrel 94 of guide sleeve assembly 92. Guide sleeve assembly 92 in the preferred embodiment functions as a drill guide and/or a screw guide. Guide sleeve assembly 92 is directed at insertion point 30 toward target zone 104 between first and second probes 56, 60.

In the preferred embodiment, arch assembly 84 is pivotally moveable relative to mount 72. Referring briefly to Figure 15, the range of motion of arch 86 is shown relative to retractor assembly 42. As shown in Figure 5, arch 86 includes a handle 89 for use by the surgeon in rotation of arch 86 relative to mount 72. End 88 fits into hole 78 shown in Figure 4. Handle 89 may also be used by the surgeon to stabilize arch assembly 84.

Arch assembly 84 can be permanently mounted to retractor assembly 42. Alternatively, arch assembly 84 can be releasably mounted to retractor assembly 84. In either case, arch assembly 84 can be pivotally moveable relative to retractor assembly 42 for movement in accordance with that illustrated in Figure 15, or non-pivotally mounted, in which case, left-handed and right-handed drill guide apparatus must be provided to drill and position screws on both sides of the spine.

Guide sleeve assembly 92 includes a barrel 94, shown in Figure 5 as being rigidly mounted to arch assembly 82. As will be described below, barrel 94 may be slidably mounted for adjustable movement along arch 86.

Received within barrel 94 is an inner guide sleeve arrangement including an outer screw sleeve 96 and an inner drill sleeve 100. Screw sleeve 96 is slidably mounted relative to barrel 94 with a friction fit. Additional structure, such as a set screw may be provided for a more secure mount. Drill sleeve 100 is slidably mounted within screw sleeve 96. A flange 102 of drill sleeve 100 engages a flange 98 of screw sleeve as shown in Figure 5. A friction fit may also be provided with respect to the engagement of screw sleeve 96 and drill sleeve 100.

The inner guide sleeve arrangement of guide sleeve assembly 92, including the screw sleeve 96 and the drill sleeve 100, is long enough to reach from the skin through the soft tissues without unnecessary retraction to the barrel 94. Once placed within barrel 94, drill sleeve 100 and/or screw sleeve 96 would rest against the entry point on the dorsal lamina for direction and control of the drill bit.

In Figure 5, target zone 104 is defined by an end of a drill bit 106. Drill bit 106 is received within drill sleeve 100. A drill stop 107 with a set screw 108 provides a stop structure on drill bit 106 to limit the amount of

insertion of drill bit 106 into drill sleeve 100. It is to be appreciated that drill stop 107 is optional. However, drill stop 107 is preferred so that target zone 104 is properly defined, and drill bit 106 does not inadvertently extend too far, or not far enough.

As shown in Figure 5, an exterior of screw sleeve 96 is provided with indicia 105 to indicate to the surgeon the distance from target zone 104 to an end 100a of drill sleeve 100 and/or screw sleeve 96. Indicia 105 can assist the surgeon in locating drill stop 107 with set screw 108 on drill bit 106 to achieve the desired drilling depth of drill bit 106. Indicia 105 is useable to calibrate the positioning of barrel 94 and drill sleeve 100.

Referring to Figure 6, drill sleeve 100 is shown removed from screw sleeve 96. Screw sleeve 96 is ready for passage of screw 110. Screw 110 enters screw sleeve 96 at end 96a. Washer 114 is positioned at an opposite end 96b of screw sleeve 96 for engagement with screw 110 as screw 110 exits screw sleeve 96. Screwdriver 112 is utilized to rotate screw 110 into channel 109 formed by drill bit 106 wherein the screw is directed toward target zone 104 to fixate facet joint 28. A pin or other elongated fixation device can be used instead of screw 110.

Screw 110 has a minimum outer dimension from the longitudinal axis such that screw 110 can pass completely through the passageway defined by screw sleeve 96. Drill sleeve 100 defines a passageway therethrough which is small than the dimension of screw 110. However, drill sleeve 100 is appropriately sized to properly guide the smaller drill bit 106 into the base. Removal of drill sleeve 100 is needed in order to allow passage of screw 110.

Arch assembly 84 or other convenient structure extending from barrel 94 provides a handle structure for the surgeon should it be desirable to use guide sleeve assembly 92 separately from retractor assembly 42.

Referring now to Figure 7, the vertebrae 33b and 33c are shown with screw 110 and washer 114 in position. A second facet joint 228 on an opposite side of the spine is processed with a second drill guide apparatus 240 to illustrate a non-pivotally mounted system with respect to arch assembly 84, and retractor assembly 42. In the case of a pivotally mounted configuration for arch assembly 84 and retractor assembly 42, as shown in Figure 15, the same drill guide apparatus 40 can be used on both sides of the spine as long as the appropriate amount of pivoting movement is provided. When switching sides, the components are rotated relative to one another to give the appropriate location and angle for the drill bit and screw. Second drill guide apparatus 240 is configured similarly to drill guide apparatus 40 shown in Figures 3 through 6. However, second drill guide apparatus 240 is configured in a mirror image to drill guide apparatus 40.

In second drill guide apparatus 240, a second guide sleeve assembly 292 extends from a second arch assembly 284, which is mounted to a second retractor assembly 242. Retractor assembly 242 retracts skin 22 to allow drilling and positioning of the screw. Drill guide apparatus 240 is usable to define target zone 304. After drilling a channel using guide sleeve assembly 292, a second screw 310 and a second washer 314 are placed as shown in Figure 8 in a like manner as screw 110 and washer 114 to fixate facet joint 228.

Referring now to Figures 5 and 7, guide sleeve assembly 92 and guide sleeve assembly 292 each pass through a portion of skin 22 and associated tissue of the patient. Such puncturing of the skin and other tissue allows for less retraction and a smaller incision, while also allowing definition of the target zone at the appropriate angle for fixation of the vertebrae.

Referring now to Figure 9, screw 110 is shown in greater detail. Head 116 of screw 110 includes a flange 118, and an outer mating surface 120, preferably hexagonally shaped, tapering toward shaft 126. Rounded corners 122 are provided at the interface between shaft 126 and outer surface 120. Shaft 126 is provided with threads 128, and a cutting flute 130 to facilitate insertion of screw 110 into the bone. Cutting flute 130 taps threads into the bone during rotation of screw 110.

Recess 124 of head 116 is configured to engage a hexagonally shaped tool to permit rotation of screw 110 by the tool. For example, the tip of tool 112 is shown in Figure 6. Other mating tools/recesses are anticipated.

As shown in Figure 9, flange 118 is provided with a cylindrical outer shape. The widest outside dimension of screw 110 at flange 118 is smaller than the inner diameter defined by screw sleeve 96, as viewed in Figure 6, such that screw 110 can pass completely through screw sleeve 96 during insertion into the bone.

Referring now to Figure 10, washer 114 is shown in greater detail. It is to be appreciated that washer 114 is optional. However, washer 114 allows for greater compression to be achieved during fixation. Washer 114 includes a bone engaging plate portion 132 having a planar cylindrical shape. An extension 134 extends centrally from bone engaging portion 132. Extension 134 includes a hexagonally shaped outer surface 136 and a hexagonally shaped inner surface 138 which defines a passage through washer 114. An end of extension 134 defines a flange engaging surface 140 for engagement with flange 118 of screw 110 during use.

As shown in Figure 11, a screw assembly is shown including screw 110 and washer 114. Screw 110 and washer 114 are shown in engagement with a substrate 142, such as bone. During insertion of screw 110, flange 118 engages

surface 140 as screw 110 advances through washer 114 and into the substrate 142. Cutting flute 130 provides a self-tapping structure to cut threads in substrate 142. Hexagonal inner surface 138 of washer 114 provides a mechanical engagement for articulation with screw 110 at outer mating surface 120, such as for further rotation into the bone, or rotation out of the bone or other substrate utilizing a tool which engages hexagonally outer surface 136. Rounded corners 122 and the tapered outer mating surface 120 of screw 110 facilitate self-centering with washer 114. Tapered outer mating surface 120 also facilitates secure engagement with extension 134 of washer 114.

Referring now to Figure 12, an alternative screw 410 is shown. Instead of a cylindrically shaped flange 118 with respect to screw 110, second screw 410 is provided with a hexagonally shaped flange 418. Hexagonally shaped flange 418 can be configured generally the same as hexagonal outer surface 136 of washer 114 to facilitate engagement with the same tool utilized to rotate washer 114. Alternatively, hexagonally shaped flange 418 can be configured slightly smaller than hexagonal outer surface 136 of washer 114. It is to be appreciated that during removal of screw 410, and washer 114 from the bone, there may reach a point where washer 114 slides down the shaft of screw 410 such that the hexagonal inner surface 138 of extension 134 does not engage the hexagonal outer mating surface 420 of screw 410. In that case, the tool used to turn washer 114, or another tool if flange 418 is sized smaller than outer surface 136, can be utilized to engage hexagonally shaped flange 418 to remove screw 410 from the bone.

Referring now to Figure 13, an alternative washer 430 is shown with a cup shaped bone engaging portion 432. Washer 430 is also shown in Figure 14 in side view which

illustrates the cup shaped configuration. As shown in Figure 13, washer 430 is engaged by screw 110. Screw 110 is rotated into the bone via recess 124. Rotation out of the bone can be achieved by engagement with surface 436 of extension 434.

Referring again to Figure 14, a screw assembly including screw 110 and cup shaped washer 430 is shown wherein a tool 150 including a handle 151 and an extending shaft 152 is provided to rotate screw assembly including screw 110 and cup shaped washer 430 together as one unit out of substrate 442. Tool 150 generally defines a T-wrench for convenient grasping by the surgeon. Shaft 152 of tool 150 includes an inner hexagonally shaped recess 154 for engagement with hexagonally shaped surface 436 of extension 434 of cup shaped washer 430. Tool 150 is moved in a direction of arrow A toward hexagonally shaped surface 436 wherein upon engagement, tool 150 is rotated in the direction of arrow B.

Referring now to Figures 16 and 17, a slidable mounting arrangement between barrel 494 and an alternative arch assembly 484 is shown. Barrel 494 is configured similarly as barrel 94 to receive screw sleeve 96 and drill sleeve 100 as shown in Figures 3 through 6. Instead of a permanent mount, a slidable mount mechanism 500 mounts barrel 494 to arch 486. Arch 486 includes a radius defining portion 847 with a radius 847a. As shown in Figure 16, barrel 494 is movable along arch 46 in the directions of arrows C depending on the location desired by the surgeon. This radial movement, along with the pivoting movement previously shown and described with respect to Figure 15, provides a three dimensional movement capability with respect to barrel 494 relative to the target zone 104.

As shown in Figure 16, arch assembly 494 mounts to retractor assembly 42 at mount 72. As shown in Figure 17, a sleeve 502 and a set screw 504 permit sliding

relative movement between barrel 494 and arch 486, and selective rigid mounting, when desired.

Referring again to Figure 4, screw sleeve 96 is shown positioned spaced apart from the vertebra 34 such that washer 114 is received therebetween. Preferably, screw sleeve 96 is slidably moved relative to barrel 94 such that a secure engagement exists between screw sleeve 96, washer 114, and vertebra 33b. A clamp may be provided by the surgeon to facilitate the secure engagement, such as by guide sleeve assembly 92 and retractor assembly 42 to engage the bone therebetween especially during the drilling operation. Eyelets on guide sleeve assembly 92, such as on flange 98 of screw sleeve 96 and on retractor assembly 42, may facilitate easy clamping with a surgical clamp.

Referring now to Figure 18, an alternative structure and method are shown with respect to placement of washer 430. Alternative drill sleeve 600 is shown with a shortened end 602 such that prior to use, washer 430 can be frictionally engaged with screw sleeve 96. During the drilling operation, drill bit 106 passes through drill sleeve 600 and washer 430. Upon removal of drill bit 106 and drill sleeve 600, screw sleeve 96 is ready for receipt of screw 110.

As shown in Figure 19, screw 110 slides through screw sleeve 96 for rotational engagement with the bone. Upon exiting screw sleeve 96, screw 110 engages washer 430 to slide washer 430 off the end of screw sleeve 96. Outer hexagonal surface 120 engages inner hexagonal surface 436 of projection 434 of washer 430. In this manner, washer 430 is automatically held in proper position until screw 110 is properly positioned to engage washer 430.

Referring now to Figures 20 through 22, alternatives to the use of drill sleeve 100 for drilling are shown. In Figure 20, a drill bit 606 is provided with an enlarged portion 610 relative to drill bit portion 608

extending therefrom to drill tip 609. Enlarged portion 610 accurately guides tip 609 by engagement with screw sleeve 96. Once drill bit 606 is removed, screw sleeve 96 is usable for receipt of the screw in the manner previously described.

When drilling at an angle into a substrate, such as bone, support of drill bit portion 608 relative to enlarged portion 610 may be desirable. Referring now to Figures 21 and 22, an alternative drill bit 624 is shown. Drill bit portion 626 is similarly configured as with respect to drill bit 606 in Figure 20. Enlarged portion 628 is similarly configured as enlarged portion 610 in Figure 20. Enlarged portion 628 is provided with two projections 632, 634 for use in facilitating rotation of a reinforcing sleeve 620 with drill bit 624 during use. Such configuration may prevent wearing of drilling portion 626 due to relative sliding. As shown in Figure 21, reinforcing sleeve 620 supports a portion of drill bit portion 626 such that tip 629 is exposed and the rest of drill bit portion 626 is supported by reinforcing sleeve 620. The drilling operation using reinforcing sleeve 620 is only to begin drilling of the channel. Once the channel is started, drill bit 624 is removed from screw sleeve 96 and reinforcing sleeve 620 is removed. At that point, the drilling operation can continue as shown in Figure 20, for example.

Preferably, although not required, retractor assembly 42 and arch assembly 84 are separate elements to facilitate ease of use wherein retractor assembly 42 can be appropriately positioned, then arch assembly 84 added. Also, it is preferred, although not required, that drill sleeve 100, and screw sleeve 96 are separate elements from barrel 94 to facilitate placement in the patient without additional dissection and retraction. In some cases, use of retractor assembly 42 and guide sleeve assembly 92

separately may be advantageous. In that case, no connecting structure between retractor assembly 42 and guide sleeve assembly 92 would be used.

In accordance with the present invention, minimized dissection is provided including avoidance of unnecessary exposure, avoidance of bleeding, and anesthesia time wherein retractor assembly 42 can be inserted blind into the anatomy such that the anatomy is defined at the target portion of the retractor and confirmed by either a palpitating finger through undisturbed tissue or an X-ray. The patient requires a drill bit to the point of entry on the bone. Even in the hands of those skilled in the art, the spinning drill bit will move about the dorsal lamina such that either suboptimal strength or penetration of delicate structures may result. Once the retractor is placed and confirmed in satisfactory position, arch assembly 84 can be seated upon the target area of the retractor reaching up and over the dorsal process, defining the anatomy such that drill sleeve 100 and screw sleeve 96 may be placed through barrel 94. Drill sleeve 100 will intersect the appropriate portion and region of the bone for the drill to begin its penetration. After the bone has been drilled, the screw, pin or other fixation structure is reliably and safely placed into the vertebra. Since the entry point of the screw in the predrilled channel is deep within the body and control of the screw is difficult, and often compounded by the tension of the surrounding tissues and bone, use of screw sleeve 96 is advantageous. By piercing the surrounding tissue with the drill sleeve and screw sleeve, less tissue damage results than if the drill, and screwdrivers were positioned around dissected and distracted tissue. Because of three dimensional and technical considerations, right and left sided arch assemblies and guide sleeve assemblies may be necessary. A pivotally mounted arch assembly 84 and retractor assembly

42 may alleviate the need for left and right handed structures. Transfixion of a lumbosacral facet joint may be accommodated either by a retractor positioned at the L5 level or a shortened probe. In the alternative, other landmarks such as the dorsal S1 foramen (a bony landmark defining neural and bony anatomy) may be used to direct and guide the drill and screw.

Drilling holes in bone or other substrate can be difficult or impossible without a drill guide to guide the drill bit. Placement of the facet screws without a drill guide apparatus 40 or similar structure in accordance with the present invention often proves unreliable and is associated with complications including suboptimal bone purchase, neurologic injury, and bleeding. In accordance with the present invention, internal spine fixation can be accomplished by accurate definition of the anatomy, accurate placement (location, angle, and depth) of the drill bit and similar instruments, accurate placement (location, angle, and depth) of the appropriate screw and other instruments, and biologically correct distribution of forces. Also, the present invention allows for convenient removal of the screw, if desired. While the option for drilling and screw placement in accordance with the invention are described above together, each may be used in the absence of the other.

A significant advantage of the drill guide apparatus 40 and the various methods described above includes the greater predictability and control of the tissue preparation during the spinal fusion surgery. Drill guide apparatus 40 more predictably defines the anatomy to be transfixed and directs the drill through complex and difficult to reach anatomy to the target area.

Another advantage is that the present invention leads to more controllable internal fixation. The screw of the present invention without the large head assembly can

be passed through the tissue with the guidance of the screw sleeve to mate with a washer structure. The washer allows for greater stress distribution than the small head of the screw. The screw sleeve and drill sleeve allow for accurate and reproducible placement of the screw without direct visualization of the entire vertebrae.

A further advantage is that the present invention leads to ease of operating procedures. This will include decreased operating time, decreased blood loss, decreased risk of infection, decreased trauma, and decreased anesthesia time. Not only do these have practical implications to the patient, but economic implications. Accurate placement of internal fixation devices allows for minimal use of foreign objects in the patient with less waste.

Another advantage is the ability to reliably remove both the washer and the screw when necessary for safe and effective removal of the internal fixation devices, such as when the screw is no longer needed. Such ease of removal which is typically done under separate anesthetic and medical situations would likewise achieve the practical and economic goals of decreased exposure to surgical complications such as those associated with anesthesia, infection, and bleeding.

Referring now to Figures 23-30, alternative drill guide apparatus are shown which are particularly useful for transfixing a facet joint with entry in the alternative insertion zone 30b as shown in Figure 4. Insertion zone 30b is ipsilateral to the intended facet joint. The entry point to the facet joint is on the near side of the spinous process. If necessary, the spinous process can be shaved to facilitate placement of the drill guide apparatus.

In Figure 23, a retractor assembly 702 includes a handle 704 with a blade end 706 for insertion into the body, and in particular to engage the bone. End 706

preferably includes at least one probe, and preferably two probes 708, 710, which are preferably threadably mounted to end 706 for removal and/or adjustability. Retractor assembly 702 includes an elongated slot 712 for receipt of a guide sleeve assembly 714 such as shown in Figures 24 and 25. Guide sleeve assembly 714 extends from retractor assembly 702 and defines guide structure for a drill bit during a drilling operation.

Guide sleeve assembly 714 slidably mounts to retractor assembly 702 via an elongated mounting projection 716 which is configured for receipt in slot 712 in a dove tail arrangement. In Figure 23, guide sleeve assembly 714 would be slidably mounted to retractor assembly 702 in the direction of arrow AA. Guide sleeve assembly 714 would slideably dismount in an opposite direction. A reverse positioning of slot 712 and projection 716 is possible, if desired. Bottom surface 713 in slot 712 is a stop surface for limiting the downward movement of guide sleeve assembly 714. It is preferred, although not required, that guide sleeve assembly 714 engage stop surface 713 during use.

Guide sleeve assembly 714 further includes a plate 718 from which mounting projection 716 extends. A set screw 720 through plate 718 permits a rigid locking of guide sleeve assembly 714 to retractor assembly 702. A spring loaded locking pin or other locking mechanisms may also be used instead. An arm 722 extends from plate 718 to body or block 724. Block 724 is provided with a passage 726 which performs the guiding function. Axis 728 of passage 726 passes through target zone 730. Variations of passage 726 in different guide sleeve assemblies 714 are possible for use with patients having different sized or shaped vertebrae, and for different sizes and shapes for individual vertebra of each person. Figure 24 illustrates possible variations of passage 726 in the direction of angle A, while maintaining a constant target zone 730.

Figure 25 illustrates variations of passage 726 in a direction of angle B while maintaining a constant target zone 730. Figure 24 also illustrates three sizes of guide sleeve assemblies represented by C_1-C_2, D_1-D_2, and E_1-E_2 for the distances of passage 726 from plate 718. These variations are with respect to the distance from retractor assembly 702 to the guiding portion of guide sleeve assembly 714 (i.e., passage 726). Such variations may be useful in the case of smaller than average sized, average sized, and larger than average sized patients. The variations in orientation regarding angle and/or size can be handled with a kit of replaceable guide sleeve assemblies 714 which have passage 726 positioned differently between assemblies to vary the guiding operation.

Stop surface 732 on block 714 provides a constant stop distance relative to target zone 730 as angles A and B are varied. Stop surface is provided with a spherical shape about target zone 730 to maintain a constant distance to target zone 730 as the angle is varied between guide sleeve assemblies.

For each size of guide sleeve assembly 714, block 724 can be formed with a consistent outer shape, such as from a metal casting, and passage 726 drilled through block 724 in the appropriate angle to effect angle variations (both angle A and angle B) between the different guide sleeve assemblies 714.

Figures 23-25 illustrate a two piece separable construction of retractor assembly 702 and guide sleeve assembly 714. Secure drill guiding is provided by the link between retractor blade 704 of retractor assembly 702 and block 724 of guide sleeve assembly 714. Passage 726 may be used only for the drilling operation, or it may be used for both the drilling operation and screw placement.

Passage 726 is sized to receive a drill bit and/or screw during use. Alternatively, passage 726 may be sized for receipt of a screw sleeve 96 and drill sleeve 100 of the type shown in Figures 5 and 6.

It is preferred that retractor assembly 702 be separable from guide sleeve assembly 714 to facilitate ease of manufacture and use. However, if desired, a more permanent mount is possible. In the case of size and angle variations for passage 726 relative to retractor assembly 702, completely different units would need to be provided. Therefore, it may be advantageous to utilize separable guide sleeve assemblies from the retractor assembly, to reduce manufacturing costs, and bulk due to storage. Also, it may be easier to size a patient by first properly locating the retractor assembly, and then attaching various guide sleeve assemblies until the proper one is selected.

Referring now to Figure 26, a portion of an alternative guide sleeve assembly 812 is shown. Guide sleeve assembly 812 mounts to retractor assembly 702 in a similar manner as guide sleeve assembly 714. Block 814 forms the guide portion. Passage 816 through block 814 is provided with a lower bushing 818 rigidly mounted to block 814. Upper bushing 820 is rigidly mounted to block 814. An end 822 of upper bushing 820 serves as a stop when drill guide 812 is used as a guide for drilling. A slidable inner sleeve 824 slidably moves relative to lower bushing 818 in the direction of arrow C. A flange 826 is engaged by a spring 830 and lower bushing 818 to maintain inner sleeve 824 in a defined region relative to block 814. End 828 of inner sleeve 824 is therefore movable relative to block 814. End 828 is utilized to securely engage the bone surface during use. Spring 830 biases inner sleeve 824 away from upper bushing 820.

Referring now to Figure 27, a portion of a further alternative guide sleeve assembly 912 is shown.

Block 914 includes an upper extended bushing 920 which has an end 922 a further distance from block 914 than end 822 relative to block 814 of guide sleeve assembly 812. Figures 26 and 27 illustrate utilizing ends 822 and 922 as drill stops to control depth of the drilling operation relative to blocks 814, 914.

Referring now to Figure 28, a drill bit 1002 is shown with a shaft 1004 and an enlarged stop 1006 which engages surface 732, end 822 or end 922 of drill guide sleeve assemblies 714, 812, 912, respectively.

Referring now to Figure 29, retractor assembly 702 with handle 704 and retractor blade end 706 is mounted to guide sleeve assembly 714. Guide sleeve assembly 714 is usable to enter the facet joint at insertion zone 30b (Figure 4). The alternative insertion zone 30a (Figure 4) is on the opposite side of the spinous process. Guide structure including an arch assembly such as shown in Figures 5-8 is usable to access insertion zone 30a to transfix the facet joint on the opposite side of the spine. In Figure 29, the same two lower vertebrae 33b, 33c are shown, as in the view of Figure 5. In Figure 29, guide sleeve assembly 714 is not shown as being engaged with stop surface 713 of slot 712 (see Figure 23). However, if desired, a raised stop surface can be provided to engage projection 716 to limit further downward movement.

Referring now to Figure 30, an alternative locking arrangement between retractor assembly 1102 and guide sleeve assembly 1114 is shown. Both retractor assembly 1102 and guide sleeve assembly 1114 are constructed in a similar manner as in Figures 23-27. However, instead of a set screw between plate 718 of guide sleeve assembly 714 and blade end 706 of retractor assembly 702, a spring loaded pin arrangement 1108 is provided. Spring loaded pin arrangement 1108 permits securable and releasable mounting of plate 1118 to blade end 1106. A

slidable pin 1124 is positioned in an enlarged bore 1120 and a concentric small bore 1122 through plate 1118. In the locked position, conical tip 1126 of pin 1122 is received in conical recess 1128 of blade end 1106. An enlarged flange 1125 of pin 1124 is positioned between an insert 1134 and a shoulder 1130. Insert 1134 is a cylindrical insert mounted to plate 1118 to trap flange 1125. A spring 1132 positioned flange 1125 and shoulder 1130 biases pin 1124 toward blade end 1106. A knob 1136 permits convenient grasping by the user to pull pin 1124 relative to plate 1118 and away from blade end 1106 to unlock guide sleeve assembly 1114. Use of spring loaded mounting arrangement 1108 permits automatic locking during use by merely aligning tip 1126 with recess 1128, such as during slidable mounting of guide sleeve assembly 1114 relative to retractor assembly 1102.

It is understood that even though numerous characteristics and advantages of the various embodiments of the present invention had been set forth in the foregoing description together with details of the structure and function of the various embodiments of the invention, this disclosure is illustrative only and changes may be made in detail, especially in matters of shape, size and arrangement of the parts within the principals of the present invention to the extent indicated by the broad general meaning of the terms in which the appended claims are expressed.

WHAT IS CLAIMED IS:

1. A drill guide apparatus comprising:

a retractor assembly including a handle, and a retractor blade extending from the handle at an angle to the handle; and

an extension from the retractor blade, the extension defining an opening for receipt of a drill bit.

2. The drill guide apparatus of claim 1, wherein the extension is a guide sleeve assembly including a body with a passage therethrough defining the opening, and an arm extending from the body to engage the retractor blade.

3 The drill guide apparatus of claim 2, further comprising a releasable mounting arrangement for selectively mounting the guide sleeve assembly to the retractor assembly.

4. The drill guide apparatus of claim 3, wherein the releasable mounting arrangement includes an elongated projection extending from one of the retractor assembly and the drill guide sleeve assembly, and an elongated slot formed in the other of the retractor assembly and the guide sleeve assembly sized for receipt of the projection.

5. The drill guide apparatus of claim 4, further comprising a lock to releasably lock the retractor assembly to the guide sleeve assembly.

6. The drill guide apparatus of claim 5, wherein the lock includes a spring loaded slidable pin.

7. The drill guide apparatus of claim 2, further comprising a plurality of guide sleeve assemblies, each

guide sleeve assembly having a different orientation of the opening through the guide sleeve assembly relative to the retractor assembly, wherein one of the guide sleeve assemblies is mountable to the retractor assembly to achieve a desired orientation of the opening relative to the retractor assembly.

8. The drill guide apparatus of claim 7, wherein the orientation of the opening varies according to angle.

9. The drill guide apparatus of claim 7, wherein the orientation of the opening varies along a longitudinal axis of the opening.

10. The drill guide apparatus of claim 1, further comprising a spring loaded lower sleeve slidably mounted within the opening of the guide sleeve assembly.

11. The drill guide apparatus of claim 1, wherein the extension includes a spherically shaped surface portion surrounding the opening.

12. A method of drilling comprising the steps of:

providing a retractor assembly;

engaging the bone with the retractor assembly;

selecting from a plurality of guide sleeve assemblies a guide sleeve assembly having a desired orientation of an opening therethrough relative to the retractor assembly;

mounting the selected guide sleeve assembly to the retractor assembly; and

drilling a hole into the bone with a drill bit passing through the opening.

13. The method of claim 12, wherein the retractor assembly engages a vertebra, and the guide sleeve assembly includes the opening positioned to guide a drill bit ipsilateral to an intended facet joint, the method further comprising the step of drilling a hole through the intended facet joint.

14. The method of claim 12, further comprising the step of engaging the bone with a spring loaded lower sleeve slideably mounted in the opening.

15. A method of transfixing a spinal facet joint comprising the steps of:

positioning a retractor assembly to engage the spine;

mounting a guide sleeve assembly to the retractor assembly;

positioning a drill bit in the guide sleeve assembly;

drilling a hole in the spine with the drill bit using the guide sleeve assembly as a guide; and

inserting a screw into the hole drilled by the drill bit.

16. A drill guide apparatus comprising:

a retractor assembly including a handle, and a retractor blade extending from the handle at an angle to the handle;

an arch assembly mounted to the retractor assembly; and

a guide sleeve assembly mounted to the arch assembly and defining an opening for receipt of a drill bit.

17. The drill guide apparatus of claim 16, further comprising a washer selectively mounted to the guide sleeve assembly.

18. The drill guide apparatus of claim 17, further comprising a screw defining a maximum outer dimension from the longitudinal axis sized smaller than the opening through the guide sleeve assembly, the screw including a head sized larger than a passage defined through the washer.

19. The drill guide apparatus of claim 16, wherein the guide sleeve assembly includes:

a barrel mounted to the arch assembly;

a screw sleeve slidably mounted within the barrel; and

a drill sleeve slidably mounted inside the screw sleeve.

20. The drill guide apparatus of claim 19, further comprising a screw defining a maximum outer dimension from the longitudinal axis sized smaller than the inside dimension of the screw sleeve, and larger than the inside dimension of the drill sleeve.

21. The drill guide apparatus of claim 19, wherein the arch assembly is pivotally mounted to the retractor assembly.

22. The drill guide apparatus of claim 21, wherein the barrel is slidably mounted to the arch assembly for movement along the arch assembly.

23. The drill guide apparatus of claim 22, further comprising a lock screw to lock the barrel to the arch assembly in the desired position.

24. The drill guide apparatus of claim 19, further comprising depth calibration markings on the screw sleeve.

25. The drill guide apparatus of claim 16, wherein the guide sleeve assembly is slidably mounted to the arch assembly for movement along the arch assembly.

26. The drill guide apparatus of claim 16, wherein the guide sleeve assembly includes a barrel and an inner sleeve slidably mounted to the barrel.

27. The drill guide apparatus of claim 26, further comprising:

depth calibration markings on the inner sleeve;

a drill bit disposed within the inner sleeve;

a drill stop sized larger than the drill bit and mounted to the drill bit to engage an end of the inner sleeve.

28. The drill guide apparatus of claim 16, wherein the retractor assembly includes a first threadably mounted probe.

29. The drill guide apparatus of claim 28, wherein the retractor assembly includes a second threadably mounted probe spaced from the first probe.

30. The drill guide apparatus of claim 29, wherein the retractor assembly includes at least three threaded holes in alignment, the first and second threaded probes each positioned in one of the threaded holes.

31. The drill guide apparatus of claim 16, further comprising:

a drill bit having a first portion defining a drilling portion with an outside diameter and a drilling tip; and a second portion disposed away from the drilling tip, the second portion having an outside diameter greater than the first portion; and

a reinforcing sleeve positioned only around a part of the first portion.

32. A retractor assembly comprising:

a handle;

a retractor blade extending at an angle from the handle to an end; and

a first threaded probe threadably mounted to the end.

33. The retractor assembly of claim 32, wherein the end defines a plurality of threaded holes, the first threaded probe positioned in one of the threaded holes.

34. The retractor assembly of claim 32, further comprising a second threaded probe threadably mounted to the end spaced from the first threaded probe.

35. The retractor assembly of claim 34, wherein the end defines at least three threaded holes in alignment, the first and second threaded probes each positioned in one of the threaded holes.

36. A retractor assembly comprising:

a handle;

a retractor blade extending at an angle from the handle to an end, the end defining a bone engaging surface, the retractor blade defining a central axis;

a first probe extending from the end, wherein the bone engaging surface of the end and the first probe define an angled region to surround a portion of bone on two sides, the first probe positioned offset from the central axis of the retractor blade.

37. The retractor assembly of claim 36, further comprising means for adjusting the amount of extension of the first probe from the end.

38. The retractor assembly of claim 36, further comprising a second probe spaced from the first probe, wherein the bone engaging surface of the end and the first and second probes cooperate to surround a portion of bone on three sides.

39. A screw assembly comprising:

a screw including:

a head having:

an outer mating surface; and

an inner tool engaging surface; and

a shaft extending from the head, the shaft including threads; and

a washer including:

a plate portion; and

a central projection extending from the plate portion and defining an inner passage for receipt of the screw, the central projection including:

an inner mating surface configured to mate with the outer mating surface of the head; and

an outer tool engaging surface.

40. The screw assembly of claim 39, wherein the outer mating surface of the head, and the inner mating surface of the central projection include at least one planar surface.

41. The screw assembly of claim 39, wherein the head includes a flange sized larger than the inner passage defined by the central projection.

42. The screw assembly of claim 41, wherein the flange includes a hex shape.

43. The screw assembly of claim 39, wherein the outer mating surface of the head includes a tapered shape tapering toward the shaft.

44. The screw assembly of claim 39, wherein the plate portion of the washer is cup-shaped.

45. A guide sleeve assembly comprising:

a barrel defining an inner passage;

a screw sleeve slideably mounted within the inner passage of the barrel, the screw sleeve including an inner passage;

a drill sleeve slideably mounted within the inner passage of the screw sleeve; and

a handle projection extending from the barrel.

46. A method of transfixing a spinal facet joint comprising the steps of:

positioning a retractor assembly to engage the spine;

mounting a guide sleeve assembly to the retractor assembly;

positioning a drill bit in the guide sleeve assembly;

drilling a hole in the spine with the drill bit using the guide sleeve assembly as a guide;

positioning a screw in the guide sleeve assembly; and

rotating the screw into the spine using the guide sleeve assembly as a guide.

47. The method of claim 46, further comprising the step of:

before positioning the screw in the guide sleeve assembly, removing a drill sleeve from the guide sleeve assembly to widen the passage through the guide sleeve assembly.

48. The method of claim 46, further comprising the step of:

positioning a washer between the guide sleeve assembly and the spine before rotating the screw into the spine.

49. The method of claim 48, further comprising the step of:

rotating the screw and the washer as a unit out of the spine.

50. The method of claim 46, wherein the step of positioning the retractor assembly to engage the spine includes the step of surrounding a portion of the spine on two sides with an end of the retractor assembly and a probe extending from the end of the retractor assembly.

51. The method of claim 48, wherein the step of mounting the guide sleeve assembly to the retractor assembly includes the step of passing at least a portion of the guide sleeve assembly through the patient's tissue.

52. A method of joining two substrate members comprising the steps of:

positioning a guide sleeve assembly adjacent to one of the substrate members;

positioning a drill bit in the guide sleeve assembly;

drilling a hole into at least one of the two substrate members with the drill bit;

positioning a screw in the guide sleeve assembly; and

rotating the screw into the two substrate members.

53. The method of claim 52, further comprising step of:

positioning a washer between the guide sleeve assembly and the one substrate member before rotating the screw into the two substrate members.

54. The method of claim 53, further comprising the step of:

interlocking the washer to the screw for simultaneous rotation.

FIG. 1

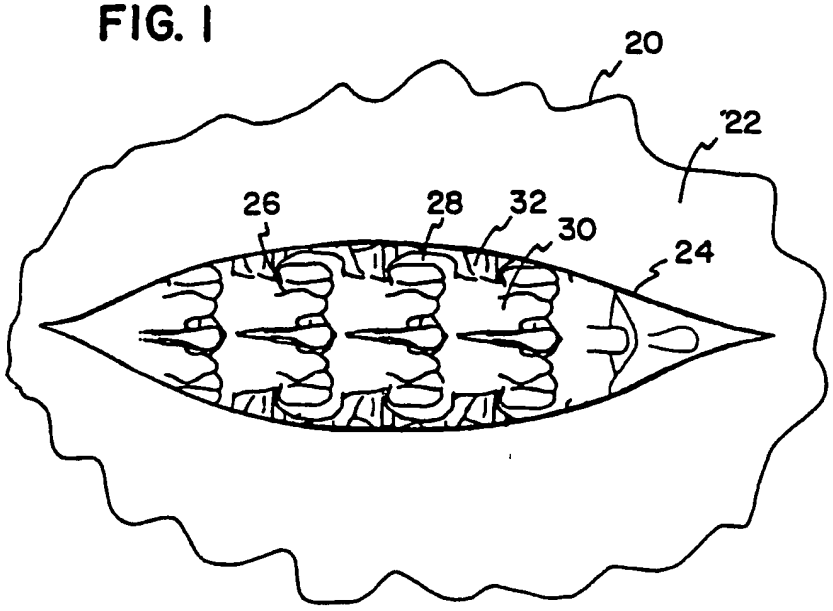

FIG. 2

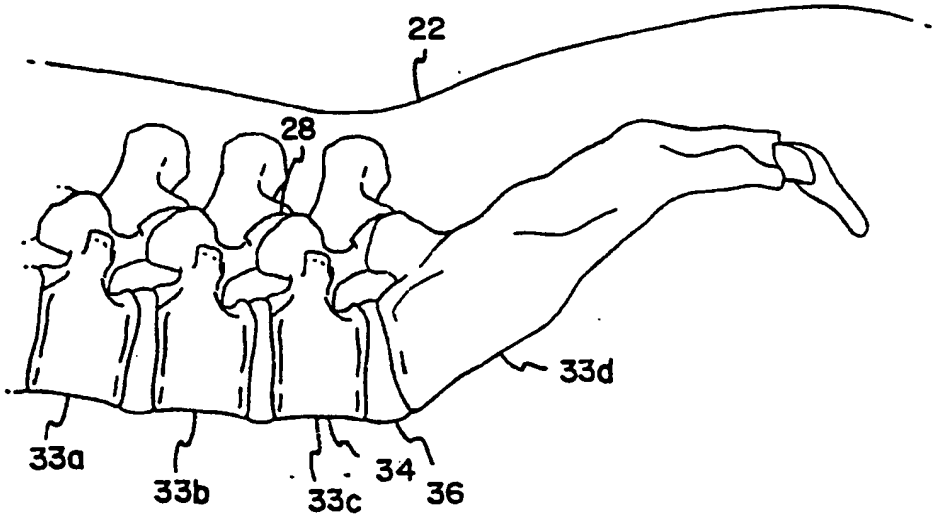

FIG. 3

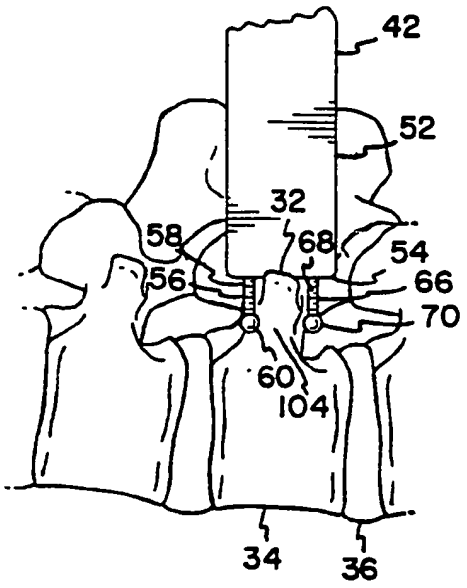
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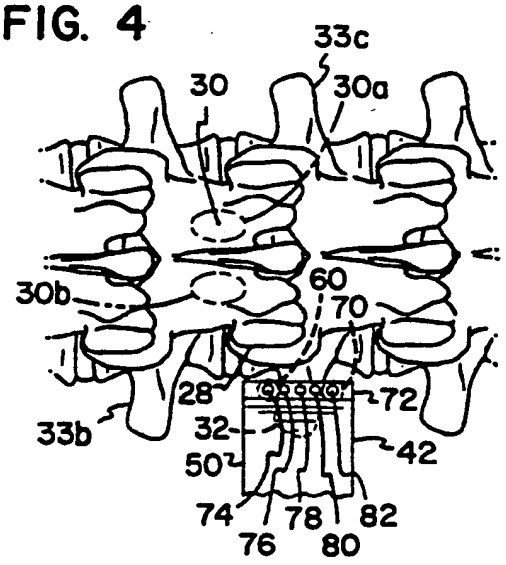
FIG. 4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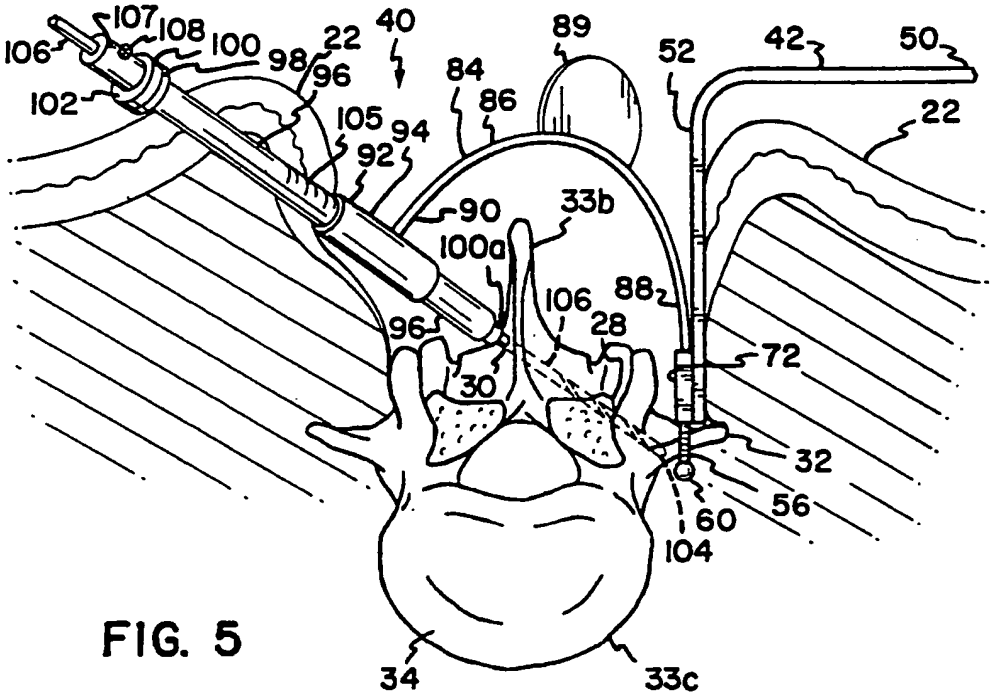
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33c

FIG. 5

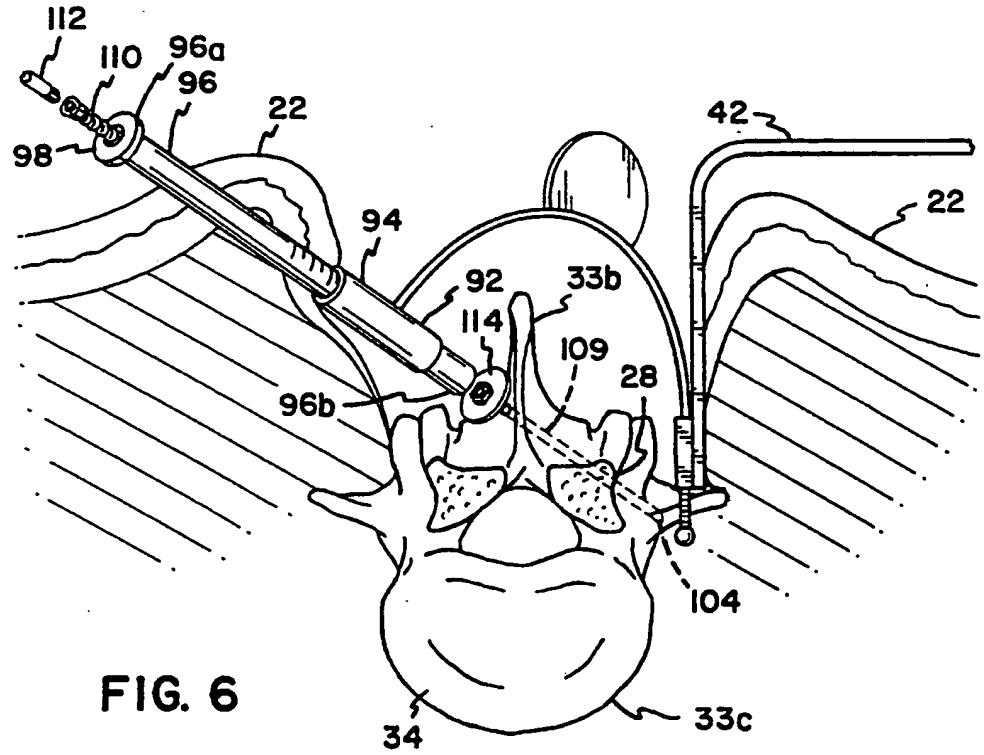
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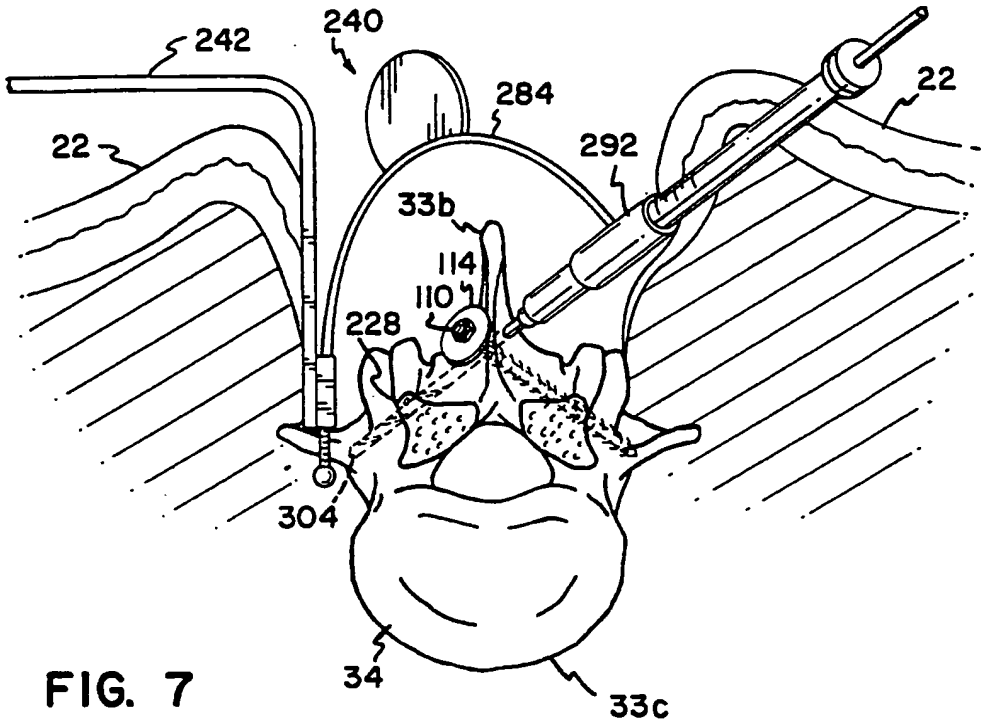
FIG. 6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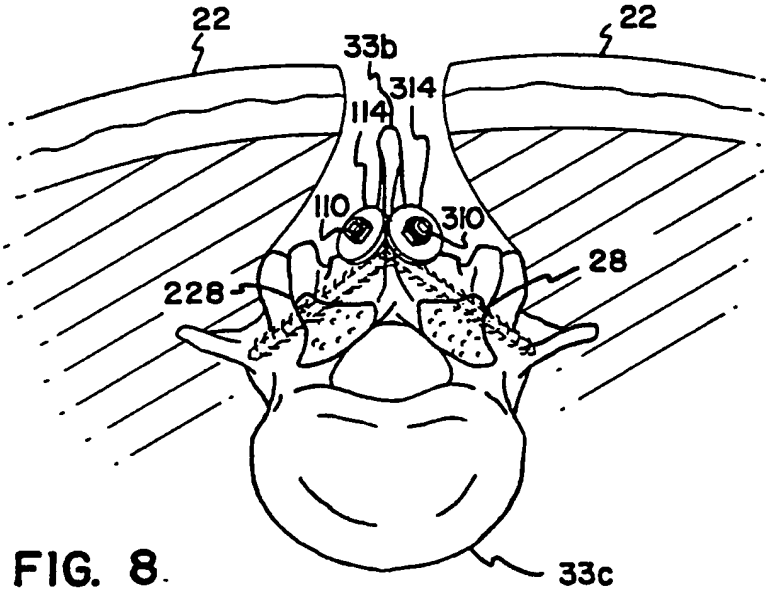
33c

FIG. 7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33c

FIG. 8

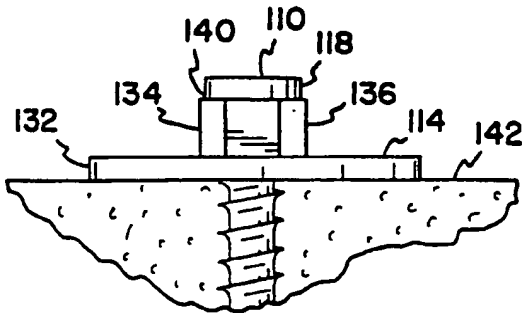
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FIG. 11

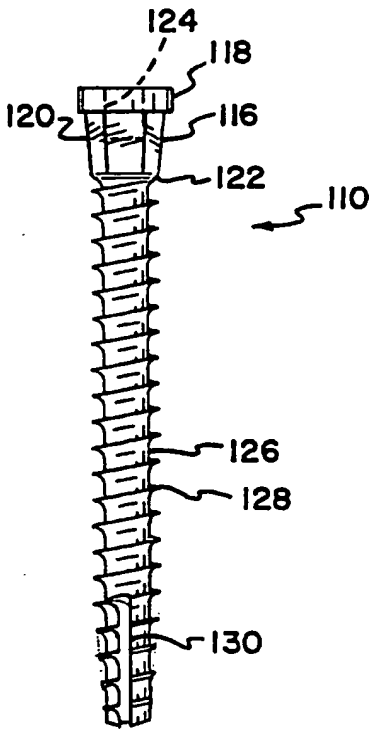
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FIG. 9

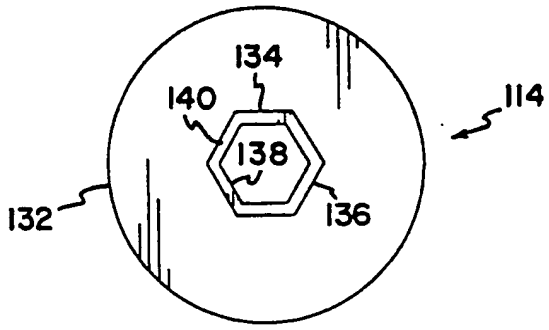

FIG. 10

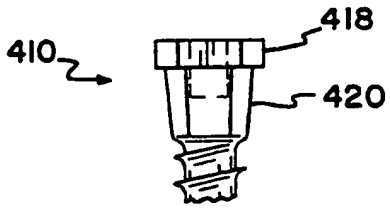

FIG. 12

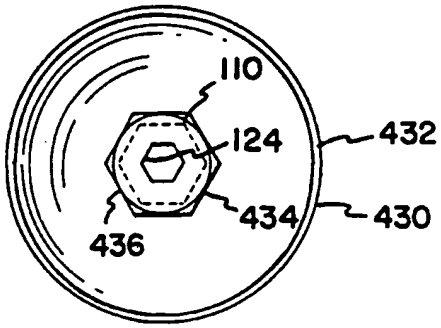
110
124
432
434
430
436

FIG. 13

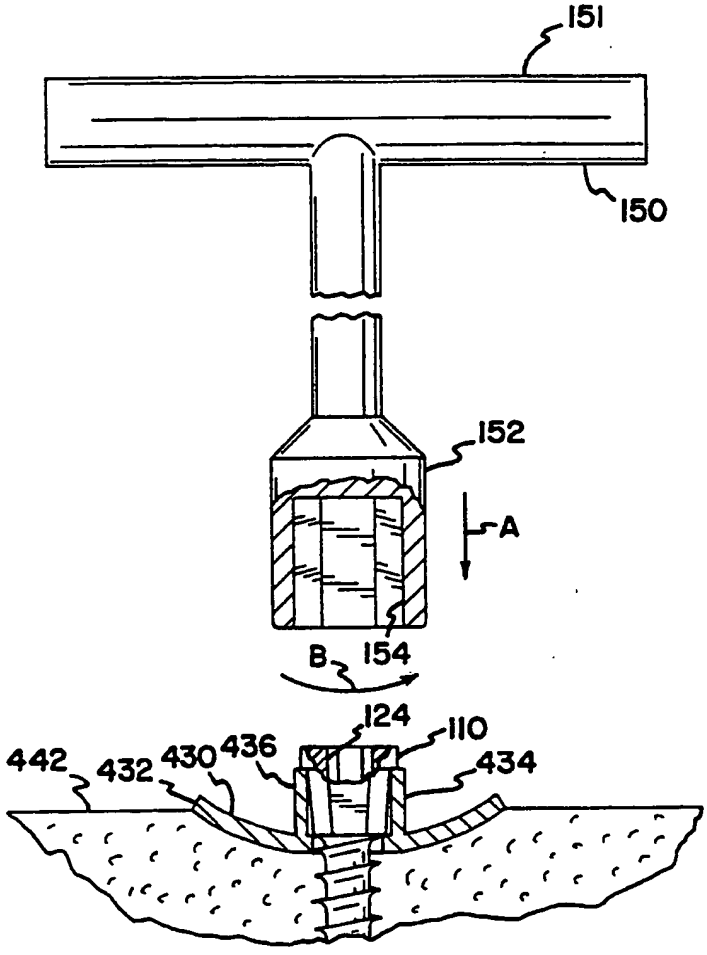
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FIG. 14

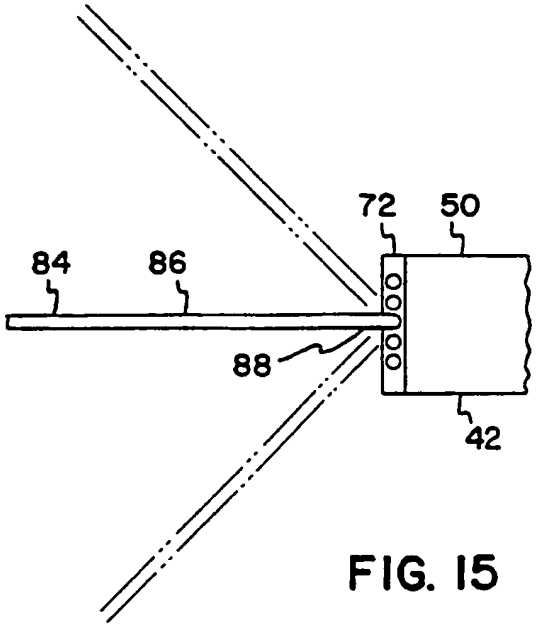

FIG. 15

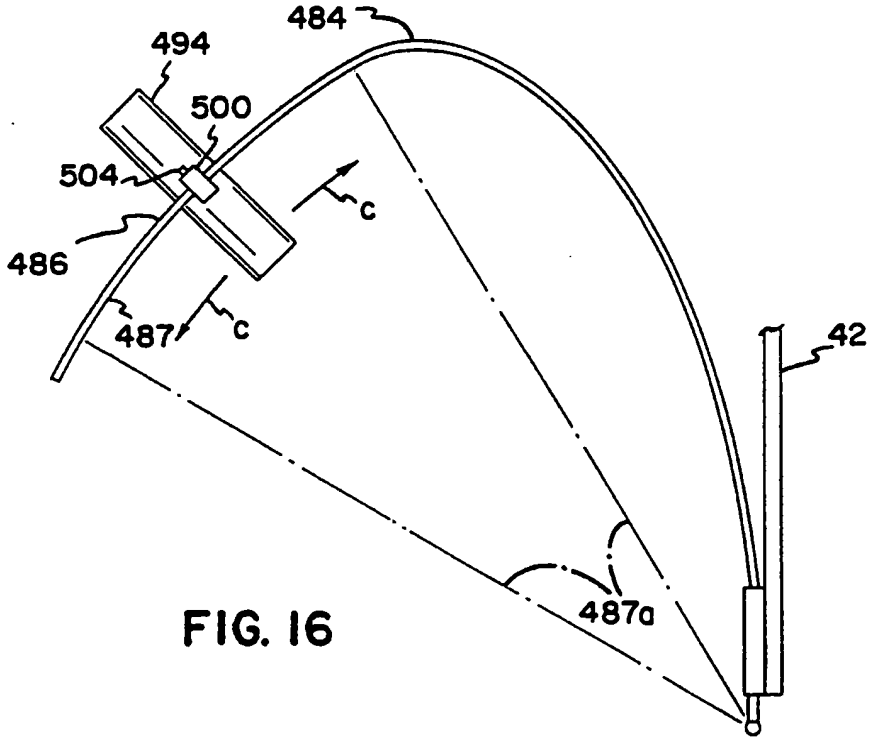

FIG. 16

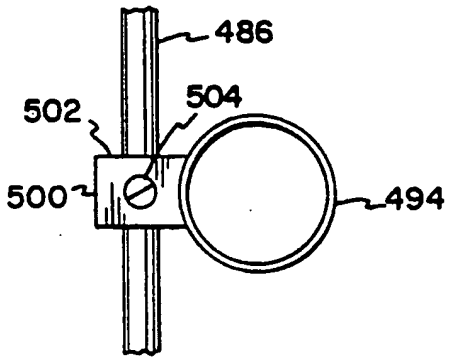

FIG. 17

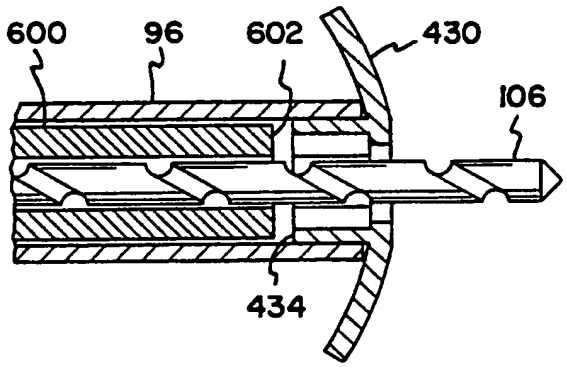

FIG. 18

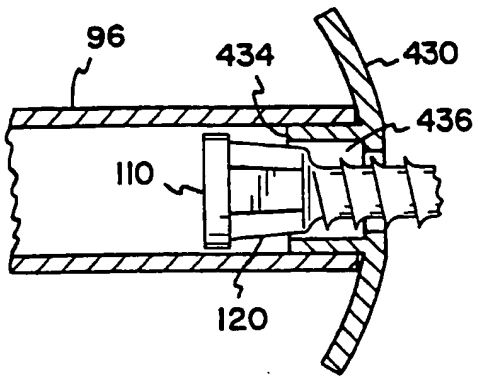

FIG. 19

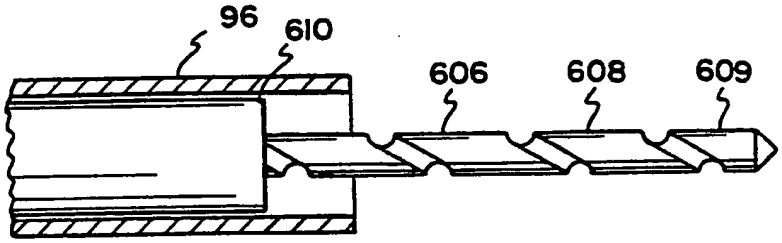

FIG. 20

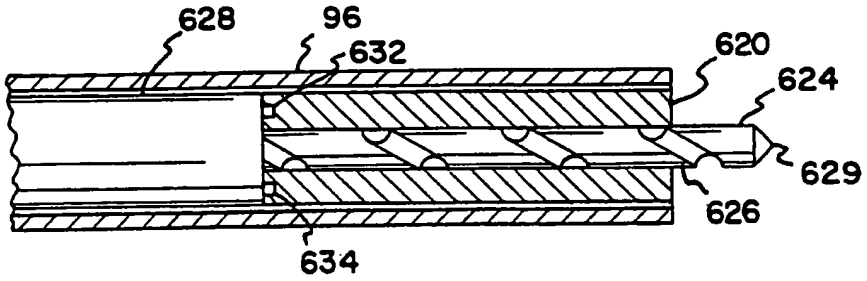

FIG. 21

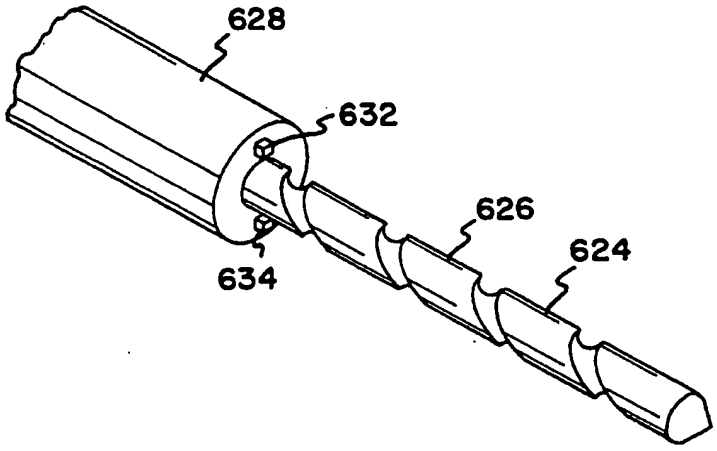

FIG. 22

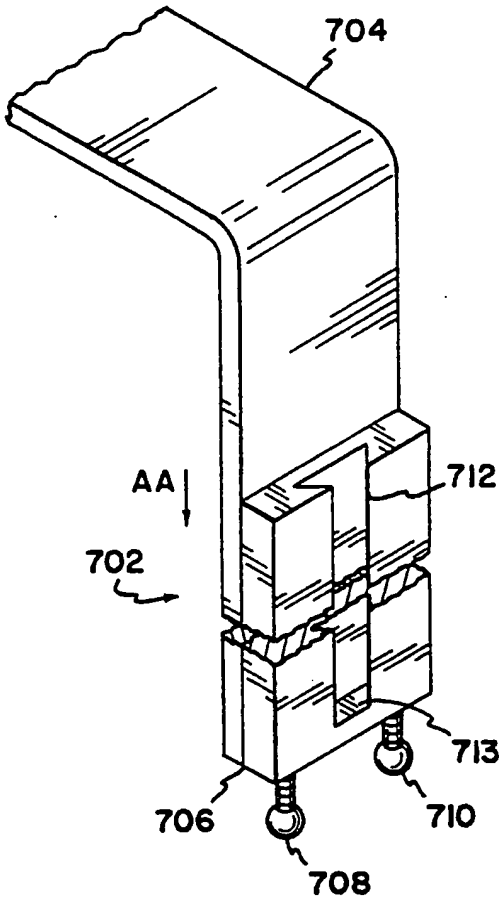

FIG. 23

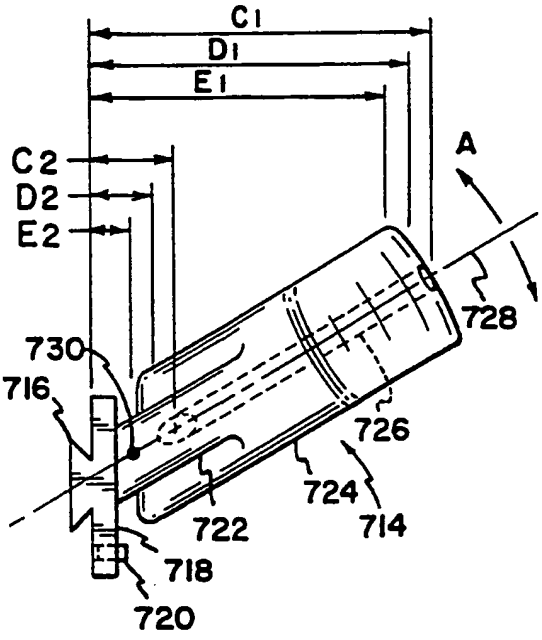

FIG. 24

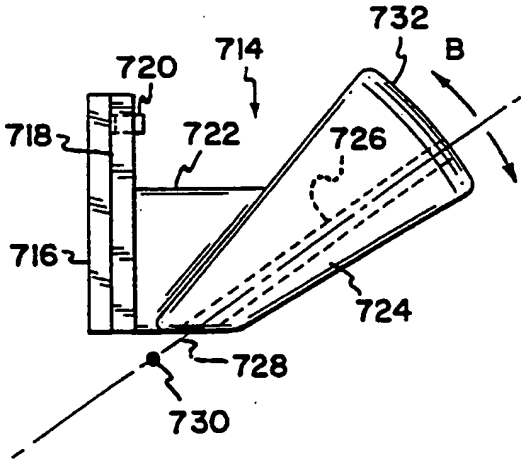

FIG. 25

FIG. 26

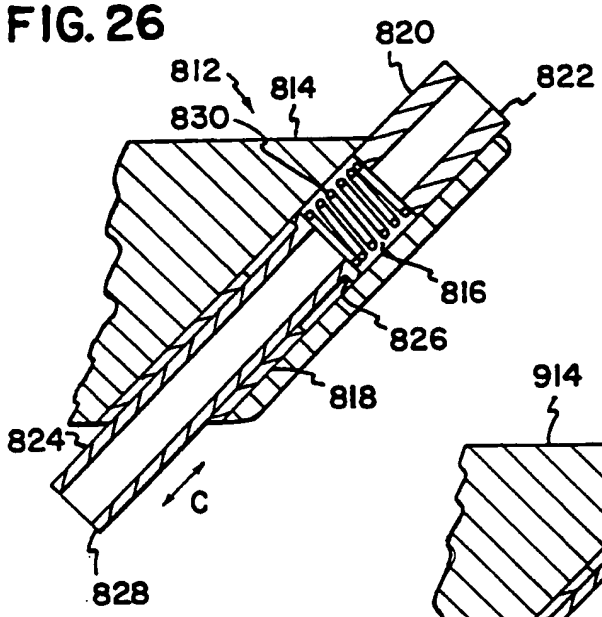

FIG. 27

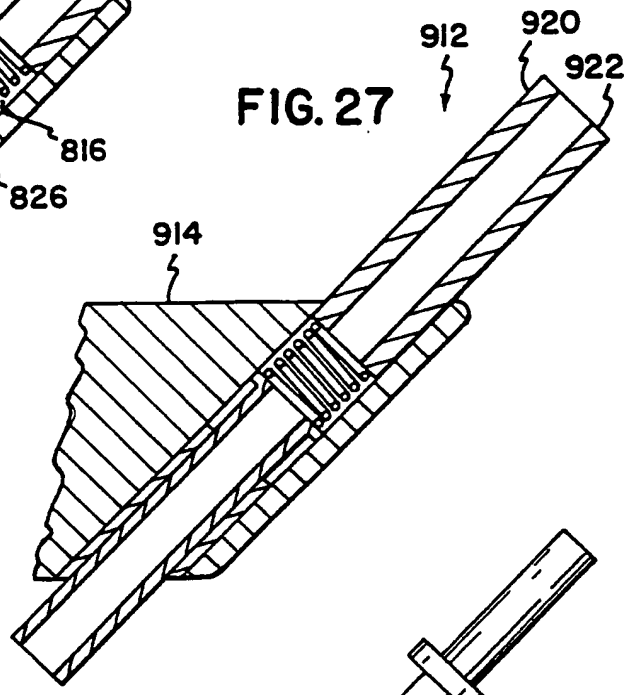

FIG. 28

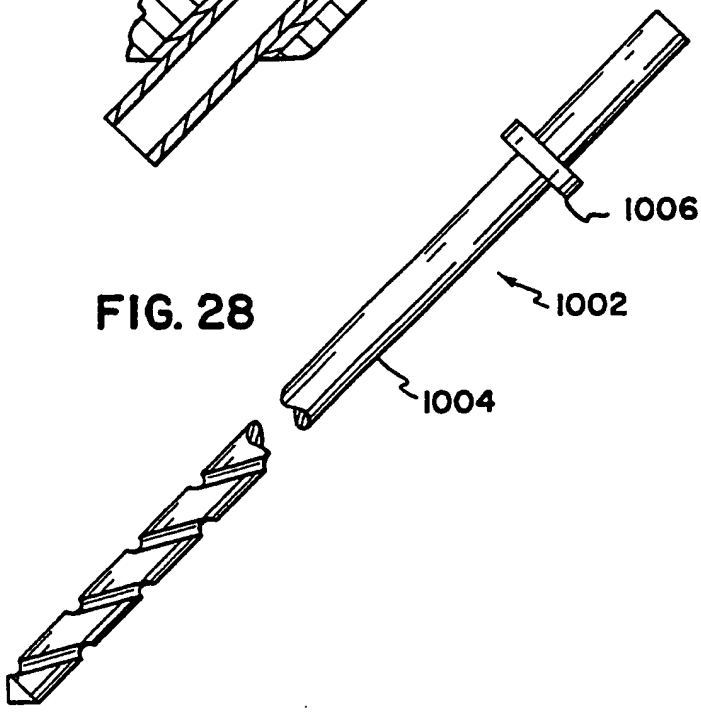

FIG. 29

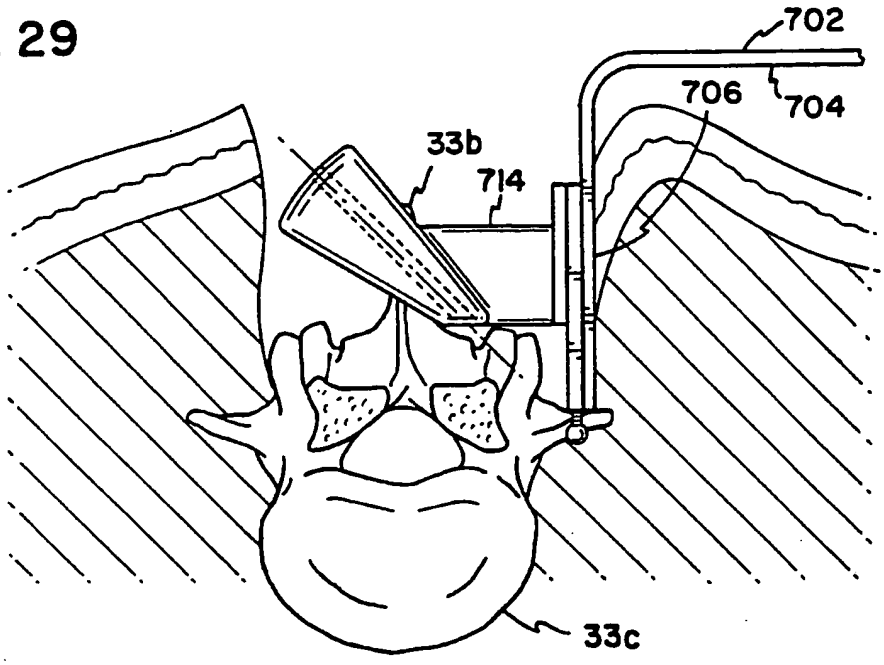
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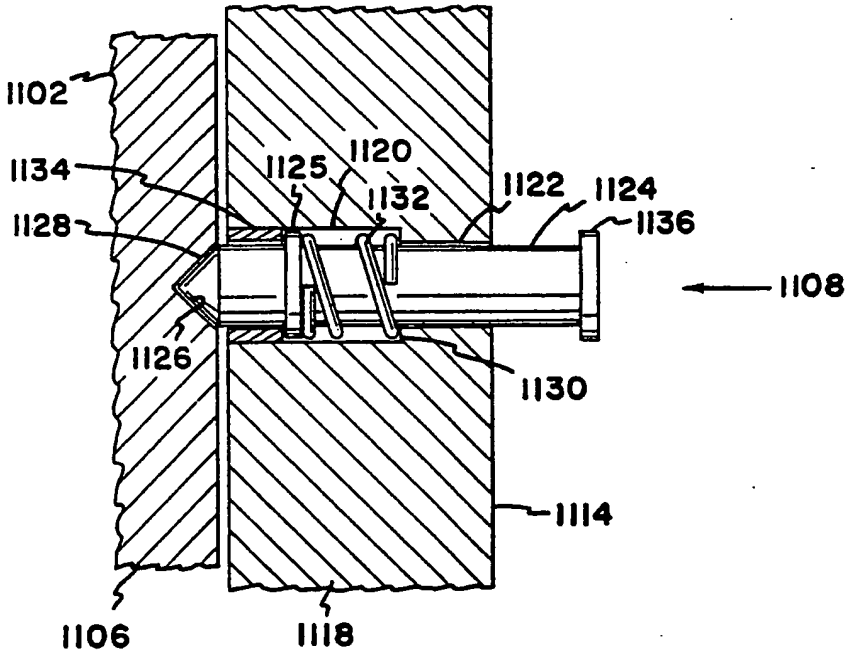
FIG. 30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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/07577

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :B23B 49/00
US CL :408/72R
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 408/72R, 4, 20, 27, 37, 41, 118-119, 145

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---- A	US, A, 4,349,945 (FOX) 21 September 1982, see whole document.	1-3, 10-11, ~~16~~-17, 19, 24, 31 ---------- 4-9, 12-15, 18, 20-23, 25-30
A	US, A, 4,208,229 (GIARDINI) 17 June 1980, see whole document.	1-11 and 16-31
A	US, A, 3,724,044 (CULPER, II) 03 April, 1973, see whole document.	1-11 and 16-31

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 26 OCTOBER 1995	Date of mailing of the international search report 14 NOV 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer FOR NANCY MULCARE Telephone No. (703) 308-0729

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/07577

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING
This ISA found multiple inventions as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s)1-11 and 16-31, drawn to a drill guide apparatus.
Group II, claim(s) 12-14, drawn to a method of drilling.
Group III, claim(s) 15 and 46-51, drawn to a method of transfixing a spine.
Group IV, claims 32-38, drawn to a retractor assembly.
Group V, claims 39-44, drawn to a screw assembly.
Group VI, claim 45, drawn to a guide sleeve.
Group VII, claims 52-54, drawn to a method of joining two substrates.

The inventions listed as Groups I-VII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, for the following reasons:

The invention listed in group I can not be grouped with any one of groups IV, V, or VI. The apparatus in each of groups IV, V and VI lack corresponding special technical features listed in group I.

Inventions IV, V and VI are related as sub-combinations disclosed as usable together in a single combination. The sub-combinations are distinct from each other because they are separately usable.
Invention IV has separate utility such as being used to merely retract. Invention V has separate utility such as being used to merely fasten.

Inventions II, III and VII, and I, IV, V and VI are related as processes and apparatus for their practice. The inventions are distinct, not only because the apparatus as claimed can be used to practice another and materially different process, but because each of the processes fail to claim the same or corresponding special technical features of each apparatus.

Inventions I, IV, V and VI can be used to guide a drill into wood unlike the process of claims 12-15 (Inventions II and III).

Invention I, unlike like the process claims of claims 52-54 (Invention VII), this Invention requires a retractor assembly.
Invention IV can be used to guide only a drill.
Invention V can be used without first drilling a bore.
Invention VI can be used to guide only a drill.

Also, the same or corresponding special technical features of the apparatus in groups I, IV, V, and VI are not claimed in the processes of groups II, III and VII.Inventions II, III and VII are disclosed as different processeswhich arenotconnectedinoperation. These groups are independent from one another because they may have different modes of operation, different functions, and they have different effects.

Invention VII is the transfixing of a human spine.
Invention II or III is drawn to a spine transfixion.
Invention III is simply the joining of two substrates, not necessarily bone. The process of this invention is a drilling process and need not join two members.